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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
10/11/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,753	CEBON ET AL.	
	Examiner	Art Unit	
	MARIANNE DIBRINO	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2010*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *20-22,25,26 and 34-37* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *20-22,25,26,34-37* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/29/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/29/10 has been entered.

Applicant's amendment filed 9/29/10 is acknowledged and has been entered.

2. Applicant' is reminded of Applicant's election of Group III (claims 20-27) and species of ISCOMATRIX as the saponin-based adjuvant comprising a sterol in Applicant's amendment filed 3/19/09.

Claims 20-22, 25, 26 and 35-37 read on the elected species.

Applicant is reminded that upon consideration of the art, examination had been extended to the species recited in instant claim 34.

Claims 20-22, 25, 26 and 34-37 and are presently being examined.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 20-22, 25, 26, 34 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amendatory material not supported by the disclosure as originally filed is as follows: "in a ratio of about 1:1 by weight" as recited in instant base claim 20. Example 1 in the specification discloses two species, *i.e.*, a ratio of 10:12 and a ratio of 1:1 falling within the genus of "in a ratio of about 1:1 by weight" represented by the said amendatory material. Applicant has support for the two disclosed species, but not the genus.

Applicant's arguments have been fully considered but are not persuasive.

Applicant's said arguments are of record in the amendment and response filed 9/29/10 at section III.

However, the ratio of 10:12 is the same ratio as 100:120, so two species are disclosed in the specification, *i.e.,* 1:1 and 10:12. The instant claim 20 recites "about 1:1" not "1:1".

5. For the purpose of prior art rejections, the filing date of the instant claims is deemed to be the filing date of the instant application, *i.e.,* 8/8/06, as the parent applications do not support the claimed limitations of the instant application. The said parent applications do not provide support for "in a ratio of about 1:1 by weight", as enunciated supra, *i.e.,* "about".

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 20-22, 25, 26, 34 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Cebon *et al* ((Proc. Amer. Soc. Clin. Oncol. 21: 6/2002, abstract 86 and presentation slides, of record, 18 pages) as evidenced by an admission in the specification at [0022], and as evidenced by Applicant's response to the response to Rule 105 Communication filed 8/2/10.

Cebon *et al* teach administering a composition comprising full length NY-ESO-1 protein and ISCOM adjuvant intramuscularly to patients with NY-ESO-1 positive tumors (tumors determined by immunohistochemistry or RT-PCR) but with minimal residual disease, in order to evaluate the safety and immunogenicity of the composition and to correlate clinical response, wherein the amount of NY-ESO-1 protein is 10, 30 or 100 ug. Cebon *et al* teach that ISCOMs are saponin-based adjuvants known to stimulate antibody responses and induce T helper cell (CD4+) and cytotoxic T lymphocyte (CD8+) responses in a variety of animal models and human clinical trials. Cebon *et al* teach intramuscular administration of their composition.

The admission in the specification at [0022] is that eligible subjects for evaluation of relapse risk were defined as those who had exhibited a cancer that expressed NY-ESO-1 as determined by either immunohistochemistry or RT-PCR, and had minimal residual disease, the same patient population taught by Cebon *et al.*

Although Cebon *et al* do not explicitly teach the amount of ISCOM administered, Cebon *et al* teach that the control amount of ISCOM administered was 100 ug. Therefore, it appears that the amount of ISCOM in the composition with NY-ESO-1 at least for the 100 ug NY-ESO-1 administration is equal in amount. Although Cebon *et al* do not correlate the clinical response in their study, immunization resulted in both humoral and cellular responses. In addition, the protocol used by Cebon *et al* is the same as that disclosed in the instant specification. Thus, it

appears that the limitation "A method for reducing the risk of relapse in a subject at risk of a relapse of a cancer, cells of which express NY-EOS-1" recited in instant base claim 20 is met by the art reference. Therefore, the claimed process appears to be the same as the process of the prior art absent a showing of differences. Since the Patent Office does not have the facilities for examining and comparing the process of the instant invention to those of the prior art, the burden is on Applicant to show a distinction between the process of the instant invention and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

In Applicant's response to the response to Rule 105 Communication filed 8/2/10 Applicant admits on the record that the data shown in the art reference correspond to example 1 in the instant specification, whereby the ratio of NY-ESO-1 protein: ISCOM on a weight to weight basis was 1:1 and 1:1.2, which meets the claim limitation "in a ratio of about 1:1 by weight" recited in instant base claim 20.

Applicant's arguments have been fully considered but are not persuasive.

Applicant's arguments are of record in the said amendment and response on pages 7-8.

The Examiner has responded to Applicant's arguments at the first three paragraphs on page 8 of Applicant's said response in the prosecution history. To reiterate, Applicant argues that Cebon does not teach or suggest methods of reducing the risk of relapse, nor that a composition comprising NY-ESO-1 protein and a saponin-based adjuvant could or should be used to reduce the risk of relapse, nor does Cebon contemplate administration of said composition to subjects at risk of relapse of a cancer which cells express NY-ESO-1. However, the admission in the specification at [0022] concerning the patient population evaluated for risk of relapse matches the art reference teaching of the patient population, and the art-taught protocol is the same protocol as Applicant's protocol (see Example 6 in the specification, for example), as enunciated supra. Thus, although Cebon *et al* do not explicitly teach that administration of the composition reduces the risk of relapse, it appears to be an inherent property of the art method that it reduces the risk of relapse, as enunciated supra.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness

from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Applicant's amendment and response filed 9/29/10 has overcome the prior rejection of record of claims 20-22, 34 and 35 under 35 U.S.C. 103(a) as being unpatentable over WO 98/14464 (IDS reference filed 11/13/09) in view of Batchu *et al* (Human Gene Therapy, 9/03, 14(14): 1333-1345) and WO 03/076455 A2 (9/18/03, IDS reference filed 11/13/09).

10. Claims 20-22, 25, 26 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/14464 (IDS reference filed 11/13/09) in view of Batchu *et al* (Human Gene Therapy, 9/03, 14(14): 1333-1345, of record) and WO 03/076455 A2 (9/18/03, IDS reference filed 11/13/09), Jager *et al* (PNAS 2000, 97(22): 12198-12203) and US 6,506,386 B1, and as evidenced by Applicant's response to the Rule 105 Communication filed 8/2/10.

WO 98/14464 teaches administering NY-ESO-1 protein in a saponin-based adjuvant to a patient with a NY-ESO-1-expressing tumor for treatment such as for treatment of breast cancer or melanoma. WO 98/14464 also teaches studying the progression and regression of cancer, and that both antibody (*i.e.,* and CD4+ T cell help for antibody production) and CTL (*i.e.,* CD8+ T cell) responses are elicited (see entire reference, especially page 19 starting at the first full paragraph, page 20 and lines 1-5 of page 21, claims 24-26, 72, Tables 3-4).

WO 98/14464 does not teach that the treatment method comprising administering NY-ESO-1 protein in a saponin based adjuvant comprises a method for reducing the risk of relapse in a subject, nor does it teach the route of administration, or that the saponin based adjuvant is an ISCOM or an ISCOMATRIX.

Batchu *et al* teach that NY-ESO-1 has been identified in melanoma, breast tumors, prostate cancers, neuroblastomas, and to various degrees in lung, bladder, hepatocellular, ovarian and thyroid cancers as well as in advanced stages of myeloma. Batchu *et al* further teach that NY-ESO-1/adjuvant based therapies (including NY-ESO-1-transduced DCs) can be used for treatment or to reduce the risk of relapse in patients by eradicating residual tumor cells, and that antibody, CD4+ and CD8+ T cell responses can all be produced to NY-ESO-1 protein (see entire reference, especially page 1334 at

column 1 at the second full paragraph, discussion section at the first three paragraphs and the last paragraph).

WO 03/076455 A2 teaches that saponin based adjuvants include ISCOMs and ISCOMATRIX and that therapeutic compositions may be administered by such routes as intramuscular or subcutaneous (especially paragraph spanning pages 35-36 and [0096]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the method of administering the composition taught by WO 98/14464 for reducing the risk of relapse of cancer patients such as taught is desirable to do by Batchu *et al.*

One of ordinary skill in the art at the time the invention was made would have been motivated to do this to eradicate residual cancer cells as taught by Batchu *et al.*

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have administered the composition intramuscularly or subcutaneously as taught by WO 03/076455 A2.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this because they are common routes of administration of therapeutic proteins as taught by WO 03/076455 A2.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the ISCOM or ISCOMATRIX adjuvants taught by WO 03/076455 A2 as the saponin-based adjuvant in the composition taught by WO 98/14464.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this because they are both saponin-based adjuvants and WO 98/14464 does not specify what the particular saponin-based

The combination of WO 98/14464, Batchu *et al* and WO 03/076455 A2 do not teach wherein the amount of protein administered is about 10 to about 500 ug, nor about 100 ug, nor that the composition comprising the protein and adjuvant is administered via an intradermal route, nor that equal amounts of protein and saponin based adjuvant are administered to the subject in a ratio of about 1:1.

Jager *et al* teach that NY-ESO-1 is a highly immunogenic cancer-testis antigen, inducing simultaneous cellular and humoral immune responses in a high percentage of patients with advanced NY-ESO-1-expressing tumors. Jager *et al* further teach administration of NY-ESO-1 CTL epitope peptides via an intradermal route of administration using 100 ug of each peptide. Jager *et al* teach monitoring disease

stabilization (see entire reference, especially abstract, introduction and materials and methods sections).

US 6,506,386 B1 discloses that vaccine compositions may be formulated to contain an ISCOM saponin-based adjuvant and an antigenic protein, the antigenic protein being present at a range of 1 to 1000 ug, including a range of 1-100 ug of protein. US 6,506,386 B1 discloses that the saponin will typically be present for human administration in the range of 1 to 100 ug per dose, and that the adjuvants of the invention are suitable for administration via any route (see entire reference, especially column 1 at lines 5-12, column 5 at lines 28-33 and lines 57-64, column 6 at lines 3-5, and column 8 at lines 53-63).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have formulated the composition of the combined references to contain equal amounts of NY-ESO-1 protein and ISCOM adjuvant, for example, 100 ug of each, and to have administered it via an intradermal route.
One of ordinary skill in the art at the time the invention was made would have been motivated to do this because US 6,506,386 B1 discloses using up to about 100 ug of saponin-based adjuvant per dose and also discloses using protein at 100 ug, and Jager *et al* also teach using 100 ug of antigen. One of ordinary skill in the art at the time the invention was made would have been motivated to administer the composition intradermally because Jager *et al* teach intradermal administration of NY-ESO-1 antigenic peptides and because US 6,506,386 B1 discloses that any route of administration is suitable.

In Applicant's response to the response to Rule 105 Communication filed 8/2/10 Applicant admits on the record that the data shown in the art reference correspond to example 1 in the instant specification, whereby the ratio of NY-ESO-1 protein: ISCOM on a weight to weight basis was 1:1 and 1:1.2, which meets the claim limitation "in a ratio of about 1:1 by weight" recited in instant base claim 20.

With regard to the claim preamble, "A method for reducing the risk of relapse in a subject at risk of relapse of a cancer", it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Applicant's arguments have been fully considered but are not persuasive.

Applicant's said arguments are of record in the amendment and response filed 9/29/11 on pages 9-13.

However, with regard to Applicant's arguments about Batchu, Batchu *et al* teach that the results obtained with gene-modified dendritic cells are not optimal in a general

sense without reference to use of NY-ESO-1, and teach that the results are due to problems associated with identification of tumor-specific immunogenic antigens coupled with low gene transfection efficiency and suboptimal expression of cloned genes in viral vectors. Batchu *et al* continues in a positive sense that NY-ESO-1 has been identified as a tumor associated antigen protein that elicits both CD4+ and CD8+ T cells, and that it is an excellent choice for CTL induction and an attractive candidate to eliminate residual myeloma cells that are responsible for the relapse of myeloma. Batchu *et al* teach that NY-ESO-1 can be used to vaccinate patients.

Furthermore, Applicant is arguing the references separately. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant's arguments about Cebon have been discussed supra.
With regard to Applicant's arguments that Jager teach the same patient population who were stabilized developed new lesions, Jager *et al* teach a subdivision of the patient population into antibody positive and antibody negative patients. Jager *et al* teach a correlation between regression and loss of antibody (especially paragraph spanning columns 1-2 on page 12202). Patients NW415, 836 and 46 were free of any new lesions for 8 months, 78 days and 112 days, respectively; patient NW731 was antibody positive. Jager *et al* teach "what was most impressive was the stabilization of disease in five of seven of the seronegative patients who developed ELSIPOT and DTH reactions after NY-ESO-1 peptide vaccination." The said reference further discusses that NW415, 836 and 46 antibody negative patients who eventually developed a single metastatic lesion while on study should arguably have been kept on vaccination, and that the development of new lesions could have resulted from emergence of antigen-loss or MHC-loss variants. Said reference states that patients with pre-existing spontaneous antibody might be considered less favorable candidates for NY-ESO-1 vaccination because the escape variants may already have been formed (especially last paragraph of reference).

The art teaches the same method steps as the claimed method steps.

11. Claims 20-22, 25, 26 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cebon *et al* ((Proc. Amer. Soc. Clin. Oncol. 21: 6/2002, abstract 86 and presentation slides, of record) in view of Jager *et al* (PNAS 2000, 97(22): 12198-12203, of record), WO 03/076455 A2 (9/18/03, IDS reference filed 11/13/09), as evidenced by an admission in the specification at [0022] and by Applicant's response to the response to Rule 105 Communication filed 8/2/10.

Cebon *et al* teach administering a composition comprising full length NY-ESO-1 protein and ISCOM adjuvant intramuscularly to patients with NY-ESO-1 positive tumors (tumors

determined by immunohistochemistry or RT-PCR) but with minimal residual disease, in order to evaluate the safety and immunogenicity of the composition and to correlate clinical response, wherein the amount of NY-ESO-1 protein at 10, 30 or 100 ug. Cebon *et al* teach that ISCOMs are saponin-based adjuvants known to stimulate antibody responses and induce T helper cell (CD4+) and cytotoxic T lymphocyte (CD8+) responses in a variety of animal models and human clinical trials. Cebon *et al* teach intramuscular administration of their composition.

Cebon *et al* do not teach that the composition comprises ISCOMATRIX rather than ISCOM and that administration may be by an intradermal route.

Jager *et al* teach that NY-ESO-1 is a highly immunogenic cancer-testis antigen, inducing simultaneous cellular and humoral immune responses in a high percentage of patients with advanced NY-ESO-1-expressing tumors. Jager *et al* further teach administration of NY-ESO-1 CTL epitope peptides via an intradermal route of administration using 100 ug of each peptide. Jager *et al* teach monitoring disease stabilization (see entire reference, especially abstract, introduction and materials and methods sections).

WO 03/076455 A2 teaches that saponin based adjuvants include ISCOMs and ISCOMATRIX and that therapeutic compositions may be administered by such routes as intramuscular or subcutaneous (especially paragraph spanning pages 35-36 and [0096]).

The admission in the specification at [0022] is that eligible subjects for evaluation of relapse risk were defined as those who had exhibited a cancer that expressed NY-ESO-1 as determined by either immunohistochemistry or RT-PCR, and had minimal residual disease, the same patient population taught by Cebon *et al.*

In Applicant's response to the response to Rule 105 Communication filed 8/2/10 Applicant admits on the record that the data shown in the art reference correspond to example 1 in the instant specification, whereby the ratio of NY-ESO-1 protein: ISCOM on a weight to weight basis was 1:1 and 1:1.2, which meets the claim limitation "in a ratio of about 1:1 by weight" recited in instant base claim 20.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used any equivalent saponin-based adjuvant in the composition taught by Cebon *et al* and any effective art known delivery route for the composition.

One of ordinary skill in the art at the time the invention was made would have been motivated to pursue the known options within is or her technical grasp in order to investigate optimization of NY-ESO-1 delivery.

Although Cebon *et al* do not explicitly teach the amount of ISCOM administered, Cebon *et al* teach that the control amount of ISCOM administered was 100 ug. Therefore, it appears that the amount of ISCOM in the composition with NY-ESO-1 at least for the 100 ug NY-ESO-1 administration is equal in amount. Although Cebon *et al* do not correlate the clinical response in their study, immunization resulted in both humoral and cellular responses. In addition, the protocol used by Cebon *et al* is the same as that disclosed in the instant specification. Although Cebon *et al* do not explicitly teach that administration of the composition reduces the risk of relapse, it is an expected property of the art method that it reduces the risk of relapse. Thus, it appears that the limitation "A method for reducing the risk of relapse in a subject at risk of a relapse of a cancer, cells of which express NY-EOS-1" recited in instant base claim 20 is met by the art reference. Therefore, the claimed process appears to be similar to the process of the prior art absent a showing of unobvious differences. Since the Patent Office does not have the facilities for examining and comparing the process of the instant invention to those of the prior art, the burden is on Applicant to show an unobvious distinction between the process of the instant invention and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

With regard to the claim preamble, "A method for reducing the risk of relapse in a subject at risk of relapse of a cancer", it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Applicant's does not argue this rejection.

12. No claim is allowed.

13. Applicant and the assignee of this application are required to provide the following information that the Examiner has determined is reasonably necessary to the examination of this application.

The Cebon reference "A2" "Cancer Vaccination" has an author who is also an inventor of the instant application.

The teaching of the said Cebon *et al* reference with regard to *in vivo* administration of the NY-ESO-1 ISCOM composition appears to be the same as the disclosure in Applicant's specification.

In the biological sciences it is customary for scientists to present their work to others at meetings with an abstract of the material present on the poster being bound and published for dissemination to scientists who could not attend the meeting in person, or in an abstract and slides being presented at the meeting. As such, the poster or slide presentation at the meeting comprises more data than what can be contained in an abstract and/or copies of the slides. Applicant is reminded that as per MPEP 2128.01:

> *IV. PUBLICLY DISPLAYED DOCUMENTS CAN CONSTITUTE A "PRINTED PUBLICATION" EVEN IF THE DURATION OF DISPLAY IS FOR ONLY A FEW DAYS AND THE DOCUMENTS ARE NOT DISSEMINATED BY COPIES OR INDEXED IN A LIBRARY OR DATABASE*
>
> A publicly displayed document where persons of ordinary skill in the art could see it and are not precluded from copying it can constitute a "printed publication," even if it is not disseminated by the distribution of reproductions or copies and/or indexed in a library or database. As stated in *In re Klopfenstein*, 380 F.3d 1345, 1348, 72 USPQ2d 1117, 1119 (Fed. Cir. 2004), "the key inquiry is whether or not a reference has been made 'publicly accessible.'" Prior to the critical date, a fourteen-slide presentation disclosing the invention was printed and pasted onto poster boards. The printed slide presentation was displayed with no confidentiality restrictions for approximately three cumulative days at two different industry events. 380 F.3d at 1347, 72 USPQ2d at 1118. The court noted that "an entirely oral presentation that includes neither slides nor copies of the presentation is without question not a 'printed publication' for the purposes of 35 U.S.C. § 102(b). Furthermore, a presentation that includes a transient display of slides is likewise not necessarily a 'printed publication.'" 380 F.3d at 1349 n.4, 72 USPQ2d at 1122 n.4. In resolving whether or not a temporarily displayed reference that was neither distributed nor indexed was nonetheless made sufficiently publicly accessible to count as a "printed publication" under 35 U.S.C. 102(b), the court considered the following factors: "the length of time the display was exhibited, the expertise of the target audience, the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and the simplicity or ease with which the material displayed could have been copied." 380 F.3d at 1350, 72 USPQ2d at 1120. Upon reviewing the above factors, the court concluded that the display "was sufficiently publicly accessible to count as a 'printed publication.'" 380 F.3d at 1352, 72 USPQ2d at 1121.<

Thus, to comply with the request for information, Applicant is requested to provide:

- A statement describing the amount of ISCOM adjuvant in each of the different protein dosage administrations, *i.e.*, for 10 ug, 30 ug and 100 ug of NY-ESO-1.
- A statement describing if reducing the risk of relapse was presented/discussed during the slide presentation.
- A statement describing all of the data that was presented and how that data is related to the data of the instant specification.
- In response to this request, Applicant is also requested to furnish:

- A statement describing additional presentations and/or abstracts presented by Applicant at scientific meetings wherein data pertinent to the subject matter was disclosed, and the contents of such disclosures, if such disclosures in fact occurred.

Note that compliance with the above requests cannot reasonably be considered burdensome since the inventors were either present at, or aware of, any disclosures of the instant claimed subject matter at scientific meetings and events prior to the filing of the instant application.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

The time period for reply to this requirement coincides with the time period for reply to this Office Action.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/G. R. Ewoldt/
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